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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,510

10/12/2005

Karl Volz

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8561

4743

7590

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EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

07/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,510	Applicant(s) VOLZ ET AL.	
	Examiner David S. Romeo	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 5-12 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12 and 16-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1105</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 03/28/2008 has been entered. Claims 1–12 and 16–21 are pending.

Applicant's election without traverse of group I, claims 1–4, 16 and 21 in the reply filed on 03/28/2008 is acknowledged.

5 Applicant's election of species (c) of claim 2 (amino acids 24-57 of SEQ ID NO: 1) in the reply filed on 03/28/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

10 Claims 5–12 and 17–20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/28/2008.

Specification

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each
15 place where a sequence is discussed. See, for example, the paragraph bridging pages 2-3, figure 4 and figure 6. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
20 The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must

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comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as “residues 14 to 243 of SEQ ID NO:23” is permissible and the fragment need not be separately presented in the “Sequence Listing.” Applicant may bring the figure(s) into compliance by amending either the figure(s) or the "Brief Description of the Drawings" to recite the appropriate sequence identifier.

Correction is required.

Claim Objections

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The analog of claim 21 could be infringed without infringing the fragment of claim 1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1 and 21, as written, do not sufficiently distinguish over proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond

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v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “Isolated” or ‘Purified.’ See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

5 basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10 (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Alberdi (J Biol Chem. 1999 Oct 29;274(44):31605-12).

Alberdi teaches a synthetic peptide 34-mer designed from amino acid positions 44-77

20 (DPFFKVPVNKLAAAVSNFGYDLRVRSSMSPTTN) of the human PEDF sequence (page 31606, left column, full paragraph 2).

The amino acid sequence of the 34-mer is identical to amino acids 24-57 of SEQ ID NO:

1.

25 Claims 1–4, 16 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bouck (U. S. Patent No. 6,797,691).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

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CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Bouck discloses a biologically anti-angiogenic active fragment of PEDF comprising amino acids 44-77 of SEQ ID NO: 1 (paragraph bridging columns 2-3; column 35, full paragraph 4), wherein the PEDF fragment comprises an altered terminus (paragraph bridging columns 24-25 through column 25, full paragraph 1), a composition comprising the biologically active fragment of PEDF and a pharmaceutical buffer or excipient, which the examiner also construes as a medical device (column 25, line 43 through column 32, line 53), and an anti-angiogenic analog of the biologically active fragment of PEDF comprising a conservative amino acid substitution (column 23, line 42 through column 24, full paragraph 1).

Amino acids 44-77 of Bouck’s SEQ ID NO: 1 are identical to amino acids 24-57 of applicants’ SEQ ID NO: 1.

Claims 1–4, 16 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bouck (WO 01/62725).

Bouck discloses an anti-angiogenic fragment of PEDF comprising amino acid residues 44 to 77 of SEQ ID NO: 1 (page 4, full paragraph 5; paragraph bridging pages 12-13; paragraph bridging pages 13-14; page 14, full paragraph 1).

Amino acid residues 44 to 77 of Bouck’s SEQ ID NO: 1 are identical to the corresponding amino acid residues of applicants’ SEQ ID NO: 1, as indicated below (Qy = applicants’ SEQ ID NO: 1; Db = Bouck’s SEQ ID NO: 1):

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Query Match 99.7%; Score 2024; DB 4; Length 418;
 Best Local Similarity 99.5%; Pred. No. 4e-176;
 Matches 396; Conservative 2; Mismatches 0; Indels 0; Gaps 0;

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5  Qy      1 NPASPPEEGSPDPDSTGALVEEEDPFFKVPVNKLAAAVSNFGYDLYRVRSSMSPTTNVLL 60
    |
Db      21 NPASPPEEGSPDPDSTGALVEEEDPFFKVPVNKLAAAVSNFGYDLYRVRSSMSPTTNVLL 80
    |
10  Qy      61 SPLSVATALSALSISLGAEQRTESIHRALYYDLISSPDHGTYKELLDTVTAPQKNLKSAS 120
    |
Db      81 SPLSVATALSALSISLGADERTESIHRALYYDLISSPDHGTYKELLDTVTAPQKNLKSAS 140
    |
    Qy     121 RIVFEKKLRIKSSFVAPLEKSYGTRPRVLTGNPRDLQEINNWWQAQMGKGLARSTKEIP 180
    |
15  Db     141 RIVFEKKLRIKSSFVAPLEKSYGTRPRVLTGNPRDLQEINNWWQAQMGKGLARSTKEIP 200
    |
    Qy     181 DEISILLGVAHFQKQWVTKFDSRKTSLEDFYLDEERTVRVPMMSDPKAVLRYGLDSDL 240
    |
20  Db     201 DEISILLGVAHFQKQWVTKFDSRKTSLEDFYLDEERTVRVPMMSDPKAVLRYGLDSDL 260
    |
    Qy     241 CKIAQLPLTGSMSSIIFFLPLKVTQNLTLIEESLTSEFIHDIDRELKTVQAVLTVPKLKLS 300
    |
Db     261 CKIAQLPLTGSMSSIIFFLPLKVTQNLTLIEESLTSEFIHDIDRELKTVQAVLTVPKLKLS 320
    |
25  Qy     301 YEGEVTKSLQEMKLQSLFSDSPDFSKITGKPIKLTQVEHRAGFEWNEDGAGTTPSPGLQPA 360
    |
Db     321 YEGEVTKSLQEMKLQSLFSDSPDFSKITGKPIKLTQVEHRAGFEWNEDGAGTTPSPGLQPA 380
    |
30  Qy     361 HLTFFLDYHLNQPFIFVLRD TDGALLFIGKILDPRGP 398
    |
Db     381 HLTFFLDYHLNQPFIFVLRD TDGALLFIGKILDPRGP 418.

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Bouck also discloses an altered terminus (page 34, full paragraph 1 through paragraph bridging pages 34-35; paragraph bridging pages 37-38), a composition comprising the biologically active fragment of PEDF and a pharmaceutical buffer or excipient, which the examiner also construes as a medical device (page 23, full paragraph 1; paragraph bridging pages 24-25; page 39, line 1 through page 50, full paragraph 1), and an anti-angiogenic analog of the biologically active fragment of PEDF comprising a conservative amino acid substitution (paragraph bridging pages 35-36) and inserted, substituted and deleted analogs (paragraph bridging pages 12-13).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10

This is a genus claim. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the PEDF fragment of claim 1. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the PEDF fragment of claim 1 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

15

20

Conclusion

No claims are allowable.

25

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

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IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID S ROMEO/
PRIMARY EXAMINER, ART UNIT 1647

DSR
JULY 6, 2008